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| 09 809,773 | 03 16 2001 | Frederick M. Ausubel | 00786 380002 | 8780 |

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EXAMINER

PARAS JR, PETER

| | |
|---------|--------------|
| ARTICLE | PAPER NUMBER |
|---------|--------------|

1037

DATE MAILED 03 11 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,773

Applicant(s)

AUSUBEL ET AL.

Examiner

Peter Paras, Jr.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-16,29 and 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5,17-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 16 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 6) ☐ Other: _____

DETAILED ACTION

Claims 1-39 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-7, 17-28 and 30 in Paper No. 9 is acknowledged.

Claims 8-16, 29, and 31-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Drawings

The formal drawings filed on December 12, 2001 are approved by the Examiner. However, some of the formal drawings are in color and do not comply with 37 CFR 1.84.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

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The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claims are directed to an isolated nematode persistently infected with an isolated pathogen, wherein the nematode is *C. elegans* and the pathogen is *Salmonella typhimurium* strain SL 1344.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to an isolated nematode infected with a pathogen. Infection of nematode by a pathogen does not alter its structure. As such the claims read on a product of nature, which is non-statutory subject matter.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-7, 17-22, 24-8 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an isolated nematode persistently infected with an isolated pathogen, wherein the pathogen is *Salmonella typhimurium* strain SL 1344. The claims are further directed to methods of screening compounds that inhibit persistent pathogenic infection in a nematode.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

While the specification has provided a description for a *C.elegans* that is persistently infected with a pathogen, the specification has failed to provide a description for the other nematodes embraced by the claims. Based upon the prior art there is expected to be structure variation among species of nematodes. The specification has not disclosed which other nematodes are embraced by the claims. There is no evidence on the record of a relationship between the structures of

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C.elegans and other nematodes embraced by the claims that would provide any reliable information about the structures of nematodes within the genus of nematodes that can be persistently infected with pathogens. There is no evidence on the record that the nematodes had known structural relationships to each other; the art indicated that there is variation between structures of nematodes. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the claimed embodiments of nematodes that are persistently infected with pathogens, other than *C. elegans*, encompassed within the genus nematodes that are persistently infected with pathogens lack a written description. The specification fails to describe what nematodes fall into this genus. The skilled artisan cannot envision the detailed chemical structure of the encompassed nematodes, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir.

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1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed of the genus of nematodes that are persistently infected with pathogens. Only a *C. elegans* has been described. Moreover, the art has recognized that there would be structural variation among the species of the genus of nematodes that are persistently infected with a pathogen. Therefore, Applicant was not in possession of the genus of nematodes as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claims 1-5, 17-20, 23-28, and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an isolated nematode persistently infected with an isolated pathogen, wherein the nematode is *C. elegans*. The claims are further directed to methods of screening compounds that inhibit persistent pathogenic infection in a nematode.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

While the specification has provided a description for bacteria that can persistently infect a nematode, the specification has failed to provide a description for the other pathogens embraced by the claims. Based upon the prior art there is expected to be structure variation among species of pathogens. The specification has not disclosed which other pathogens are embraced by the claims. There is no evidence on the record of a relationship between the structures of bacteria and other pathogens embraced by the claims that would provide any reliable information about the structures of pathogens within the genus of pathogens that can persistently infect a nematode. There is no evidence on the record that the pathogens had known structural

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relationships to each other; the art indicated that there is variation between structures of pathogens. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the claimed embodiments of pathogens that can persistently infect nematodes, other than bacteria, encompassed within the genus pathogens that can persistently infect nematodes lack a written description. The specification fails to describe what pathogens fall into this genus. The skilled artisan cannot envision the detailed chemical structure of the encompassed pathogens, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be

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unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed of the genus of pathogens that can persistently infect a nematode. Only bacteria have been described. Moreover, the art has recognized that there would be structural variation among the species of the genus of pathogens that can persistently infect a nematode. Therefore, Applicant was not in possession of the genus of pathogens as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is directed to a method of screening for a compound that inhibits a persistent pathogenic infection in a nematode wherein the compound is a peptide, peptidomimetic, antibody, or fragment thereof.

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The fragments of peptides, peptidomimetics and antibodies encompassed within the genus of peptides, peptidomimetics, and antibodies for use in the claimed method have not been disclosed. Based upon the prior art there is expected to be variation among the species of peptides, peptidomimetics, and antibodies because the art is replete with different species of peptides, peptidomimetics and antibodies. The specification discloses that peptides, peptidomimetics, and antibodies can be used in the claimed screening method and does not disclose fragments of peptides, peptidomimetics, and antibodies that can be used in the claimed methods. There is no evidence on the record of a relationship between the structure of any of the fragments of peptides, peptidomimetics, and antibodies and the peptides, peptidomimetics, and antibodies that would provide any reliable information about the structure of molecules within the genus. There is no evidence on the record that the fragments had a known structural relationship to any other peptides, peptidomimetics, and antibodies; the art indicated that there is variation between the structures of the peptides, peptidomimetics, and antibodies embraced by the claims. There is no evidence of record that would indicate that any of the claimed fragments, even have the biological activity of encompassed peptides, peptidomimetics, and antibodies. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus, because fragments of peptides, peptidomimetics, and antibodies are not representative of the claimed genus. Consequently, since Applicant has only described peptides, peptidomimetics and antibodies and since the art recognized variation among

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the species of the genus of peptides, peptidomimetics, and antibodies, the fragments were not representative of the claimed genus. Therefore, Applicant was not in possession of the fragments of peptides, peptidomimetics, and antibodies as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claims 1-7, 17-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a *C. elegans* persistently infected with a bacterium and methods of using the same to screen for compounds does not reasonably provide enablement for all other nematodes and pathogens embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to an isolated nematode persistently infected with an isolated pathogen, wherein the pathogen is *Salmonella typhimurium* strain SL 1344 and the nematode is *C. elegans*. The claims are further directed to methods of screening compounds that inhibit persistent pathogenic infection in a nematode.

The specification discusses that the invention features a nematode persistently infected with a pathogen. See page 2. The specification discusses that such

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nematodes can be used in methods for screening compounds that inhibit a persistent pathogenic infection in a nematode. See pages 3. While the specification provides extensive teachings pertaining to *C. elegans* persistently infected with a bacteria and use of such in the methods as claimed, the specification fails to provide any relevant teachings or specific guidance with regard to the other nematodes and other pathogens embraced by the claims. Given the lack of guidance provided by the specification it would have required undue experimentation to practice the claimed invention with the other nematodes embraced by the claims.

While the specification has provided guidance for use of a *C. elegans* persistently infected with a bacterium to practice the claimed invention, the specification has not provided relevant teachings or guidance for use of other nematodes and pathogens embraced by the claims. The specification has contemplated that other nematodes and pathogens may be used in practicing the claimed invention. See the specification at pages 1-6. However, the specification has failed to recite which other nematodes and pathogens could be used to practice the claimed invention. Moreover, the specification has failed to provide any guidance, working examples, or relevant teachings that would allow the skilled artisan to use nematodes other than a *C. elegans* or pathogens other than bacteria when practicing the claimed invention. The specification has also not provided any correlation between use of *C. elegans* and bacteria with use any other nematode and pathogen in the claimed invention so that the skilled artisan could extrapolate use of a *C. elegans* and bacteria to use of other nematodes and other pathogens. As previously stated the specification has not even identified which other

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nematodes or pathogens could be used to practice the claimed invention. A mere statement that other nematodes exist and could be used is not sufficient to enable the breadth of the claims as directed to any nematode persistently infected with any pathogen. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See *Genentech Inc. v. Novo Nordisk A/S* 42 USPQ2d 1001, 1997. In this case the starting material that has not been disclosed is any other nematode persistently infected with any other pathogen embraced by the claims.

Given the lack of guidance provided by the instant specification with regard to other nematodes embraced by the claims it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 20 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 18 is indefinite as written. The claim requires that the pathogen expresses a detectable gene. The claim is indefinite because it is the expression product of the gene that is detected and not the gene itself. Appropriate correction is required.

Claim 20 recites the limitation "mutated pathogen" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "inhibition of pathogenicity" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 28 depends from claim 27.

Claim 27 is confusing as written. The claim is confusing because it requires that the inhibition of pathogenicity be measured by a salmonellae/*C.elegans* killing assay but does not require either salmonella or *C. elegans*. Appropriate correction is required. Claim 28 depends from claim 27.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan et al (PNAS, 1999, 96:2408-2413; IDS ref.).

The claims are directed to an isolated nematode persistently infected with an isolated pathogen, wherein the pathogen expresses a detectable marker, and wherein the nematode is an L4 larval stage worm, wherein the pathogen colonizes the intestine of the nematode, and wherein the nematode is *C. elegans*.

Tan et al teach *C. elegans* that have been infected with *Pseudomonas aeruginosa* strain PA14. See the abstract, page 2408, the Material and Methods section, and throughout the entire document. Tan et al teach different *Pseudomonas* strains that express different detectable proteins that can be used as markers. See pages 2410-2411, as well as Table 1 on page 2411. Tan et al teach L4 stage *C. elegans* are seeded on culture plates containing different *Pseudomonas* strains. See the Materials and Methods section. Since *C. elegans* feed on *Pseudomonas* it is inherent that *Pseudomonas* is found in the *C. elegans* intestinal tract. See page 2408, column 2, at the top.

Thus, the teachings of Tan et al anticipate all the limitation of the claimed invention.

Claims 1-5, 17-20, 23-26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ausubel et al (1998, WO 98/50080; IDS ref).

The claims are directed to an isolated nematode persistently infected with an isolated pathogen, wherein the pathogen expresses a detectable marker, and wherein the nematode is an L4 larval stage worm, wherein the pathogen colonizes the intestine of the nematode, and wherein the nematode is *C. elegans*. The claims are further

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directed to methods of screening for a compound that inhibits a persistent pathogenic infection in a nematode.

Ausubel et al teach a *C. elegans* that has been infected with *Pseudomonas aeruginosa* strain PA14. Ausubel et al further teach that *C. elegans* (L4 stage) are placed on a lawn of mutant PA14 to assess the killing capacity of PA14. Since *C. elegans* feed on *Pseudomonas* it is inherent that *Pseudomonas* is found in the *C. elegans* intestinal tract. See pages 23-24 as well as page 5 at the bottom where a definition of "inhibiting a pathogen" has been provided (the scope of the definition includes inhibiting an infection). Since some of the mutant PA14 kill at a lesser rate, it is inherent that there is less colonization in the *C. elegans* intestinal tract. Finally, Ausubel et al teach that such infected *C. elegans* can be used in assays that screen for compounds that may inhibit a pathogen, wherein the pathogen is a bacterium, such as PA14. See pages 3-4. On page 54 Ausubel et al describe compounds, which can be used in the screening assay. The compounds are obtained from a library and can include peptides and other organic compounds such as saccharides, lipids and nucleic acid compounds.

Thus, the teachings of Ausubel et al anticipate all of the instant claim limitations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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PETER PARAS
PATENT EXAMINER

